

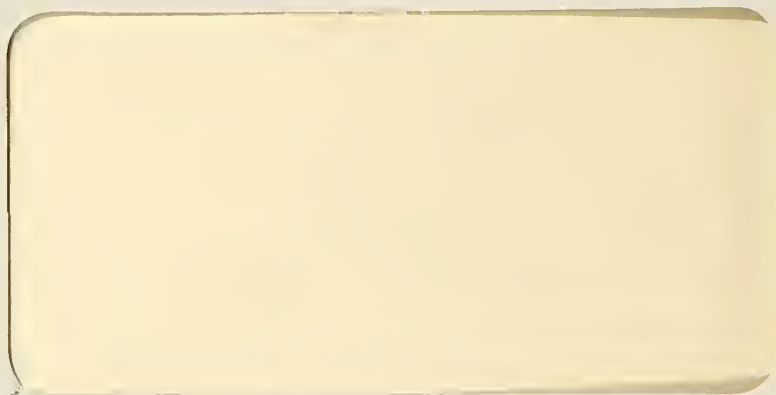
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U.S. Department of Agriculture
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Subject:

FOOD ADDITIVE PETITION

Petitioners:

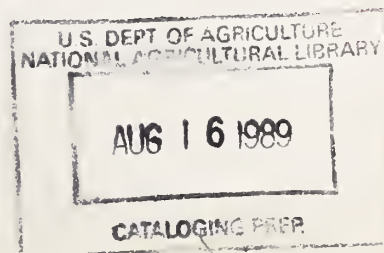
U.S. Department of Agriculture
Washington, DC

U.S. Atomic Energy Commission
Washington, DC

Name and Use of the
Proposed food Additive:

Gamma Radiation from Cobalt-60 or
Cesium-137 will be used to disinfect
papaya and thus prevent the establish-
ment of certain quarantined fruit
flies on mainland U.S.A.

Revised June 1974



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I. Fact Sheet

A. Purpose

The use of gamma radiation from cobalt-60 or cesium-137 to disinfect papaya fruit and thus prevent movement of certain quarantined fruit flies to the continental U.S.A.

B. Level of Additive and Technical Effect

Treatment by gamma radiation at a minimum absorbed dose of 26 krad will prevent development of eggs or larvae of the tephritid flies Dacus dorsalis Hendel, Ceratitidis capitata (Wiedmann) and Dacus cucurbitae Coquillett to the adult fruit fly for which a quarantine has been established. This treatment meets security requirements established for practical quarantine regulations.

C. Method of Application and Acceptability

Papaya (Carica papaya sp.), in insect-proof packages, which have or have not been pre-heated with hot water are subjected to gamma irradiation to an absorbed dose of not less than 26 krad nor more than 75 krad from sealed sources of either cobalt-60 or cesium-137 either in a continuous mode or batch operation. No post-harvest additives will be applied to the fresh fruit before or after radiation treatment. The treatment produces no detectable residues. Irradiation within the specified dose range can be applied to packaged fruit in all marketable stages of maturity or ripeness without adverse effect on the physical, sensory, and nutritional qualities.

D. Effect of Additives on Diets

Fresh papaya is a desirable fruit to be included in a daily diet and is a rich source of ascorbic acid.

Annual per capita consumption of whole fresh fruit in areas of readily available natural supplies is less than 17 pounds (44 ounces of dry solids). The maximum daily per capita consumption probably will be less than 1.0 pound of whole fruit or 1 ounce of dry solids.

E. Specifics of Irradiation

The source of cobalt-60 or cesium-137 doubly encapsulated in type 316L stainless steel or equivalent and producing gamma rays with energies of 1.17 Mev and 1.33 Mev (cobalt-60) and 0.66 Mev (cesium-137). The exposure should be such that the fruit receives an absorbed dose of no less than 26 krad and not more than 75 krad. The total dose may be delivered on a continuous or intermittent basis and monitored by positive control of cumulative exposure time. Methods of dosimetry will follow those generally recommended.

F. Proposed Safety Measures

No special provision for atmospheric or temperature control will be required except for adequate ventilation to remove ozone and nitrogen oxides from the radiation facility. The packages of treated product will be physically separated from

the non-treated and will be positively identified by marks or labels. The packing premises shall have protection from natural populations of tephritid flies.

G. Packaging and Storage

After the elected hot-water pretreatment, followed by suitable drying, the papaya will be graded for quality and maturity and packaged in FDA approved materials for contact with food during irradiation. The packages will be sealed to meet quarantine requirements and moved to the irradiation facility where they will then be irradiated. After treatment, refrigeration may be employed. The papaya will remain in the sealed package until it reaches a destination in a fruit fly free area.

H. Wholesomeness

There is no induced or residual radioactivity resulting from exposure to the energies emitted by cobalt-60 or cesium-137. Radiation disinfestation of fruit alone or in combination with hot-water treatment does not result in loss or ascorbic acid or carotenoid pigments.

Long-term animal feeding studies using three species of animals plus short term genetic susceptibility studies have demonstrated no differences attributable to radiation when these animals were fed normal diets incorporating frozen papaya puree prepared from fruit treated at a 75 krad minimum

absorbed dose or a 210 krad maximum absorbed dose.

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Introduction

Radiation treatment of papaya at a minimum absorbed dose of 26 krad will assure disinfestation of fruit infested by eggs or larvae of tephritid flies. If approved, the treatment will favor improved papaya assembly and packing operations. Consumers will find advantages as fruit can be harvested at more advanced stages of maturity when flavor is near its peak. There are no detectable residues, nor changes in composition or quality factors as a result of this treatment.

Changes in handling requirements will affect many operational stages. Present USDA quarantine regulations requiring disinfestation treatment by fumigation or vapor-heat methods (Charts 1 & 2) are batch processes that impose up to 24 hour handling delays and increase the chances for loss in quality. Radiation will reduce the delays now occurring by permitting continuous flow of the product from the time it is received at the packing plant until it is shipped to the continental U.S. (Chart 2).

The batch hot-water treatment system can be replaced by a continuous flow or tunnel-type system. This change allows continuous movement of papaya directly into packaging, treatment and post-treatment storage. Hot-water treatment is necessary to reduce chances of post-harvest decay by microorganisms and irradiation will not replace this step.

Fumigation, one of the present practices, requires that the product be treated at temperatures of 70° F. (21° C) or higher (II-1).

CHART 3

PAPAYA TREATING AND PACKING OPERATIONS FUMIGATION TREATMENT

Flow Diagrams

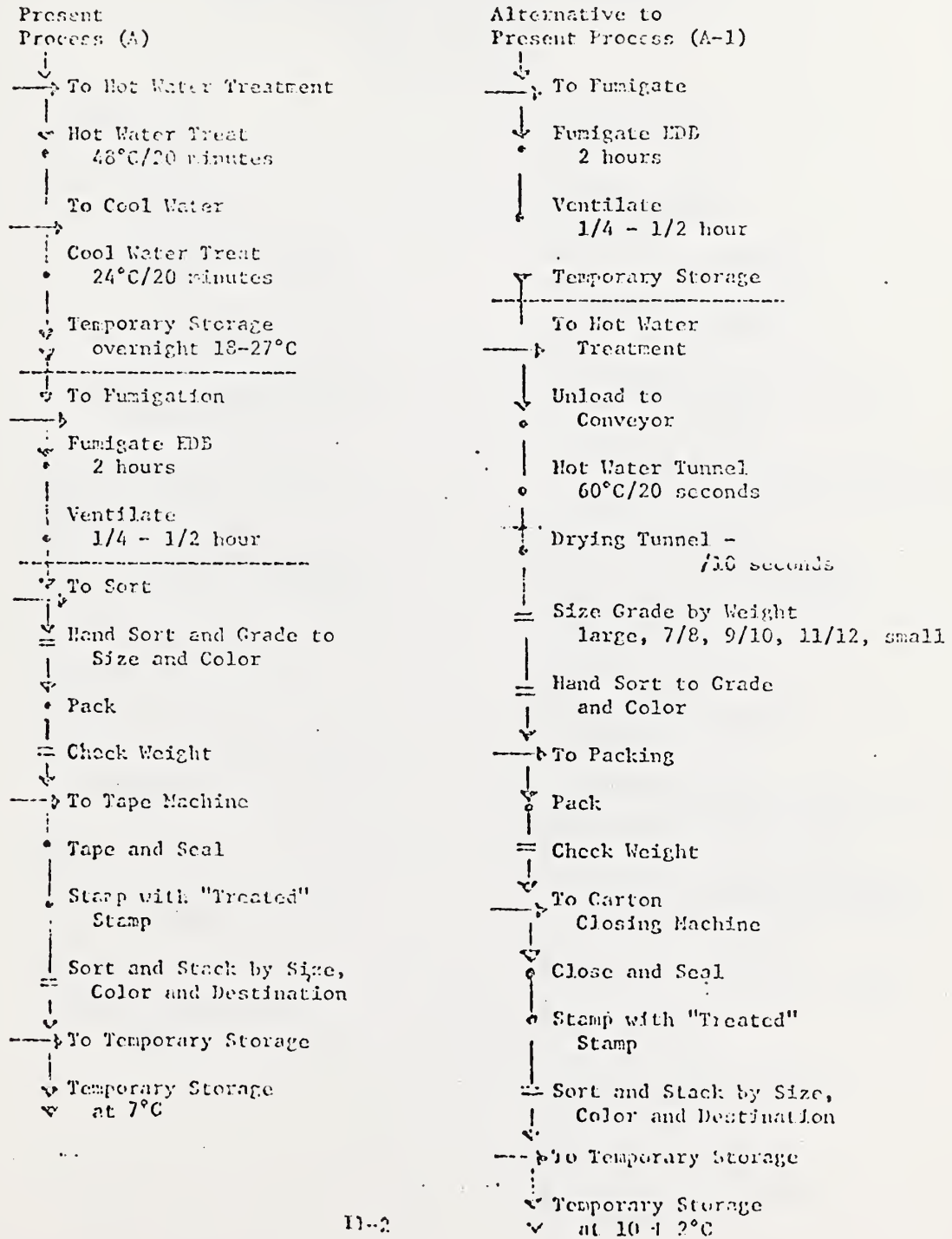
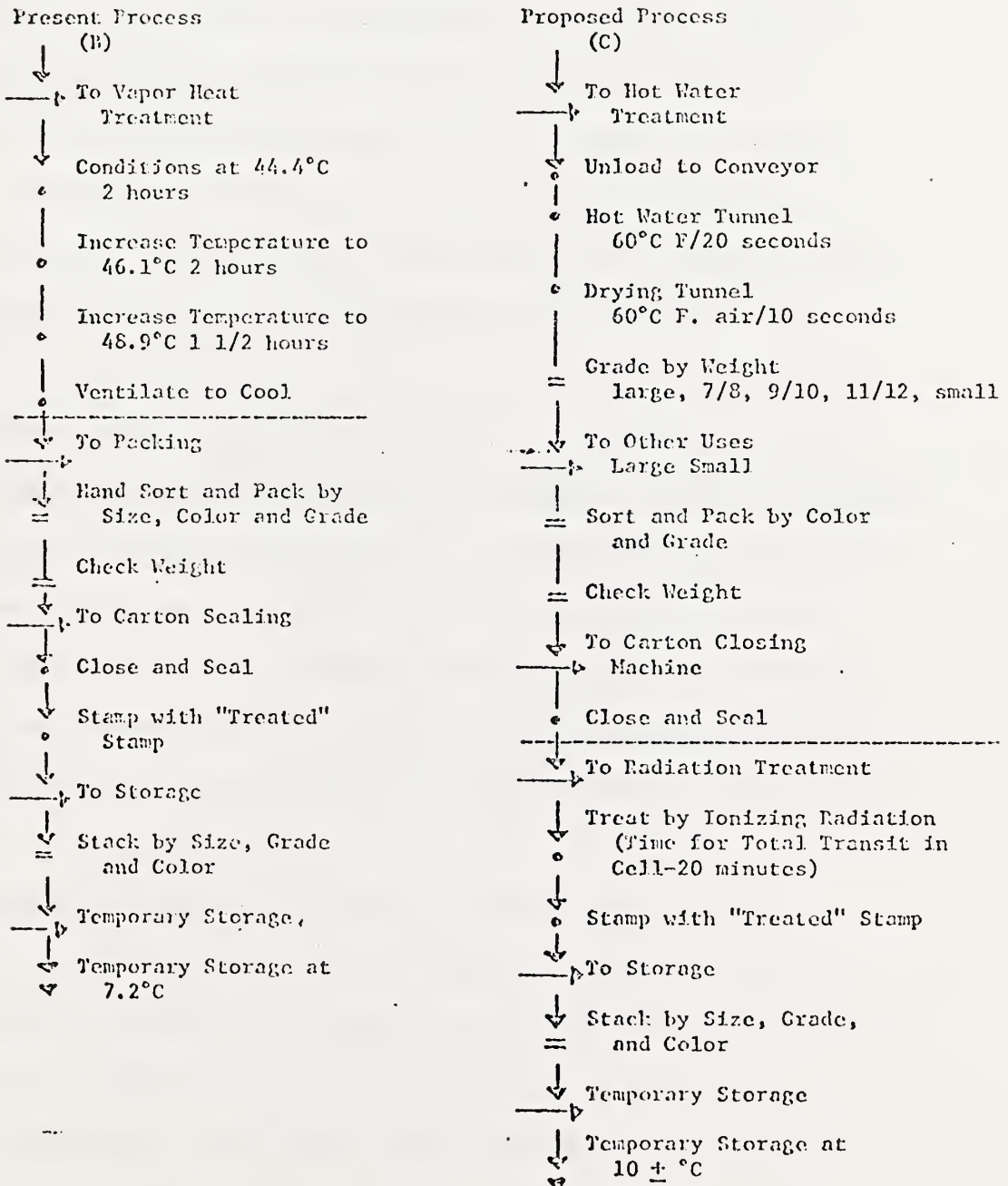


CHART 2

PAPAYA TREATING AND PACKING OPERATIONS OTHER TREATMENTS

Flow Diagrams



In practice the fruit is held at room temperature for a period of time after hot-water treatment - usually overnight. Elimination of this 20 to 24 hour time delay, from harvest to chilling and/or shipment, will permit handling of fruit at a more desirable stage of maturity.

Vapor-heat treatment, an alternate process meeting quarantine requirements, not only induces earlier ripening but requires at least an 8 3/4 hour processing step (II-1). Significant losses in weight, and change in flavor, aroma, and texture can result from this treatment. Savings both during processing and subsequent handling would be expected by replacing this type of disinfestation treatment by radiation.

Package Changes: Packaging changes are possible and these can improve economies gained by radiation processing. Shredded newspaper, which is now used as a package filler in contact with the fruit will not be permitted, once the radiation process is adopted. Kraft paper, fiberboard and poly-cellular plastic materials such as polystyrene and related materials are FDA approved packaging materials for radiation processing (II-2) and only such approved material will be used.

Procedural Changes: In addition to permitting the economies of a continuous flow system, a radiation processing plant can provide other savings, since papaya can be graded, hot-water treated, packaged and chilled before treatment. The radiation facility can treat packaged fruit immediately before loading into the shipping

container, reducing chances for reinfestation and gaining economies in handling. This process can service and accommodate individual packers by allowing them to accumulate sufficient quantities for efficient operations. The chilled product can be held for up to five days prior to processing. Such an arrangement would affect additional economies by reducing the need for manpower to meet peak demands in the harvesting and processing of papaya.

Market Changes: Marketing benefits can be accrued by the use of radiation. Fruits can be picked at a more advanced stage of maturity before treatment, meeting the changing demands of the consumer. In many cases the market calls for riper fruit and this presently poses a problem for the present disinfestation process and presupposes that fruits will be picked at or near mature green to 1/4 color stages before treatment and for shipment to mainland markets. USDA, Plant Quarantine Service, probably will need to review present fumigation requirements should the demand for a more mature fruit grow, unless radiation treatment is adopted. Any change in the fumigation requirements would require further testing and evaluation of the potential hazard from chemical residues.

Irradiated papaya develop to a full color stage at the same rate as untreated fruit. However, studies have shown that untreated fruit soften more rapidly than do irradiated fruit. This delay in softening of irradiated fruit has definite advantages for the distributor and the retailer, for a fruit which is at its most

attractive color stage can be displayed without losses due to rapid softening. The consumer can also benefit in that the product can be taken home and stored at room temperatures for longer periods without loss of quality (II-3), pp. 50-1).

In conclusion, radiation disinfestation can achieve economies in packaging and in reducing the labor costs of packaging and processing operations. It can shorten the time required from harvest to consumer thus improving the quality of the fruit at the time of consumption. There are no added chemical residues such as is found in the EDB process (II-4).

Adoption of radiation disinfestation of papaya at a minimum absorbed dose of 26 krad will meet USDA-APHIS quarantine security requirements.

Summary of Petition

Section A: Identity

Exposure of papaya to gamma radiation energy of less than 2.2 Mev is the specific subject of this petition. This section describes the design, construction and radiation characteristics of the irradiators used to conduct the studies in support of this petition.

Systems and procedures employed to define the dose delivered to the irradiated products are also described and supported by appended data for both design calculations and measurements. Process control, operational parameters and recommended procedures are also reviewed with respect to establishing and maintaining the desired treatment dose and providing the basis for product quality control.

Section B: Use

Tephritid fly infestations potentially hazardous to fruit producing areas are controlled by exposing commercial packages of fruit to gamma radiation energy at a minimum absorbed dose of 26 krad. Present USDA authorized quarantine treatments for fruit subject to infestation by various tephritid fly species of quarantine importance from Hawaii and other tropical and sub-tropical areas are not entirely satisfactory. A more effective treatment is needed to prevent the entry of fruit flies and the consequent economic losses to the continental United States. Exposure to gamma radiation provides a method that can replace existing methods that either cause evident

sensory changes in the fresh product, leave chemical residues, or are under challenge as to effectiveness.

The proposed treatment by gamma radiation will prevent the introduction of adult Oriental, Dacus dorsalis Hendel, Mediterranean Ceratitidis capitata (Wiedemann), and Melon, Dacus cucurbitae Coquillett, fruit flies to the continental U.S. A minimum absorbed dose of 26 krad of gamma radiation is established as that which meets the probit 9 level of security.

Recommended dose for a given radiation facility can be controlled by monitoring and controlling conveyer speed. This routine monitoring can be supplemented by radiation dosimetry methods. The labeling requirements shall meet the specifications required by the Food and Drug Act.

Irradiated papayas are expected to be consumed as part of the fresh fruit component of the diet. Desirable product qualities are not impaired by the treatment.

Section C: Technical Effect

Treatment of papaya by gamma radiation from cobalt-60 or cesium-137, at an absorbed dose of not less than 26 krad will prevent the emergence of adult flies from irradiated egg or larval stages of three species of tephritid flies: Dacus dorsalis, Dacus cucurbita and will meet the required level of quarantine security. or Ceratitidis capitata/ Adult forms are not expected to be present, due to the time of harvesting and method of pretreatment, but if present they will be sterilized. Studies have established that treatment at a maximum absorbed dose of 75 krad will allow commercially feasible operations without inducing physical or sensory changes in the fruit.

The treatment can be applied to papaya in all stages of maturity or ripeness without altering desirable physical, nutritional or sensory quality attributes or market shelf-life and meets the security requirements that USDA deems necessary to prevent introduction of viable flies into the mainland U.S.

The approved treatment would be applied to papayas, packaged in FDA approved materials, in such a manner as to prevent reinfestation of fruit destined for shipment to areas quarantined against fruit-fly infestation, specifically the continental United States.

Detailed data on the effectiveness of disinfestation treatment of papaya are provided in a series of reports by the University of Hawaii, College of Tropical Agriculture, Hawaii Development Irradiator, and the USDA-ARS Fruit Fly investigation Laboratory.

Section D: Methods for Determining Additive

Since there are no known detectable changes in composition of papaya treated at absorbed doses in excess of the maximum absorbed dose of 75 krad there are no known analytical methods which can usefully provide objective, practical, reliable and quantitative indicators of absorbed dose within individual fruit. There are no successful reliable go/no go indicator methods to determine exposure of product to the dose range of less than 75 krad. Therefore, dose control during treatment will depend upon well properly established monitoring procedures as described in Section A.

Monitoring will consist of time cycle recordings of the package conveyor speed and dwell times. These will establish the

irradiation exposure to the commodity once the irradiator and each specific package geometry to be used have been characterized and calibrated with "primary" chemical dosimetry and allow more rapid correction of process errors than actual dosimetry. Phantom packages with appropriately placed "secondary" dosimeters (previously cross-calibrated with the "primary" dosimeters) can also be used daily to directly verify total dose, dose rates, and dose distributions within the package.

References:

- II-1 Code of Federal regulations Title 7, Agriculture, Chapter III, Animal and Plant Health Inspection Service, Department of Agriculture, Part 318.13-4b, Administrative Instructions approving ethylene dibromide fumigation, and Part 318.13-4c, Administrative instructions prescribing methods of vapor heat treatment of certain fruits and vegetables from Hawaii.
- II-2 Code of Federal Regulations Title 21, Food and Drugs, Chapter I, Food and Drug Administration, Department of Health, Education and Welfare. Part 121, Food Additives Subpart F, Food additives resulting from contact with containers or equipment and food additives otherwise affecting food, 121.2543 Packaging materials for use during the irradiation of prepackaged foods, and Subpart G, Radiation and radiation sources intended for use in production processing and handling of food, 121.3003 Low-dose gamma radiation for the treatment of food.
- II-3 Hawaii State Department of Agriculture and USAEC, Hawaii Food Irradiation Program, NVO-374-17 (Vol. 1 and 2), 1970.
- II-4 Federal Register: Sept 23, 1970, 35FR, 14768, Subpart C, Pesticide Regulations, pg. 21.
Section E: Safety (to be furnished)
Section F: Proposed regulation (see Section F)

III. PETITION

SECTION A: IDENTITY

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III. PETITION

Section A: IDENTITY

1. Summary

Exposure of papaya to gamma radiation energy of less than 2.2 Mev is the specific subject of this petition. This section describes the design, construction and radiation characteristics of the radionuclide irradiators used to conduct the studies in support of this petition.

Systems and procedures employed to define the dose delivered to the irradiated products are also described and supported by appended data for both design calculations and measurements. Process control, operational parameters and recommended procedures are also reviewed with respect to establishing and maintaining the desired treatment dose and providing the basis for product quality control.

2. Identity of Radiation

The specific food additive which is the subject of this petition is gamma radiation emanating from sealed-source units containing either cobalt-60 or cesium-137. The radiation energy is less than 2.2 Mev.

3. Methods of Encapsulation

a. Cobalt-60

The standard Brookhaven National Laboratory (BNL) source, one of several cobalt-60 source types that can be used, consists of a strip of cobalt approximately 12 inches long x 0.060 inches

thick x 0.640 inches wide. It is doubly encapsulated in stainless steel (type 316L) sheaths, once before activation and once after activation, and has final dimensions of 0.150 inches thick x 0.800 inches wide x 13-9/16 inches long (A-1 and A-2).

These cobalt-60 sources are first calibrated for curie content, then assembled into plaques, in arrays designed to yield nearly uniform radiation dose distributions for any particular irradiation unit. Other equivalent commercially available cobalt-60 sources can be used for food irradiation.

b. Cesium-137

The BNL standard cesium-137 source is prepared by stacking 12 compressed pellets of cesium-137 chloride (each pellet approximately 1/4 inch thick x 1 inch long x 1 inch wide) inside of a stainless steel sheath. This sheath is sealed by welding and a second encapsulation is applied. Stainless steel (type 316L) is used at each encapsulation step, resulting in a total wall thickness of 0.04 inch. The final source element dimensions are approximately 13.344 inches long x 1.25 inches wide x 0.375 inch thick (A-2).

There are other equivalent cesium-137 sources available that can be used for food irradiation.

4. Engineering Data, Irradiator Design Characteristics and Flux Considerations.

Engineering data and design reports, including initial curie content plus experimental and theoretical calculations of radiation flux are presented in the Master File AEC-MF-1 entitled, "Dosimetry and Irradiation Design Characteristics," Appendices V, and VI, and VII.

The irradiator used in this study was the Hawaiian Development Irradiator (HDI) which is a single direction, single slab, two pass irradiator system (A-3). The HDI has added versatility in that it has a variable source strength. This is accomplished through the use of eight source modules which can be used in any number and in any combination of plaque positions. Additionally, the source-to-target distance can be altered by movement of the process conveyor.

The irradiation system (Fig. A from reference A-5) consists primarily of: 1) source modules and elevator, 2) process conveyor, 3) transport conveyor, 4) package loading station and, 5) water treatment system. This irradiator can treat semi-commercial quantities of a wide variety of packaged commodities at disinfestation or pasteurization doses.

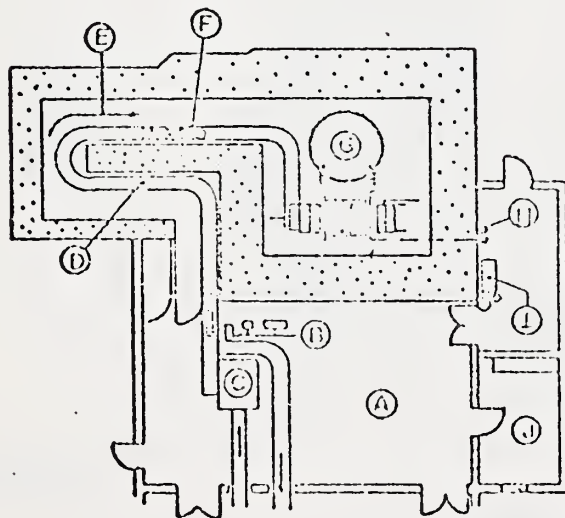
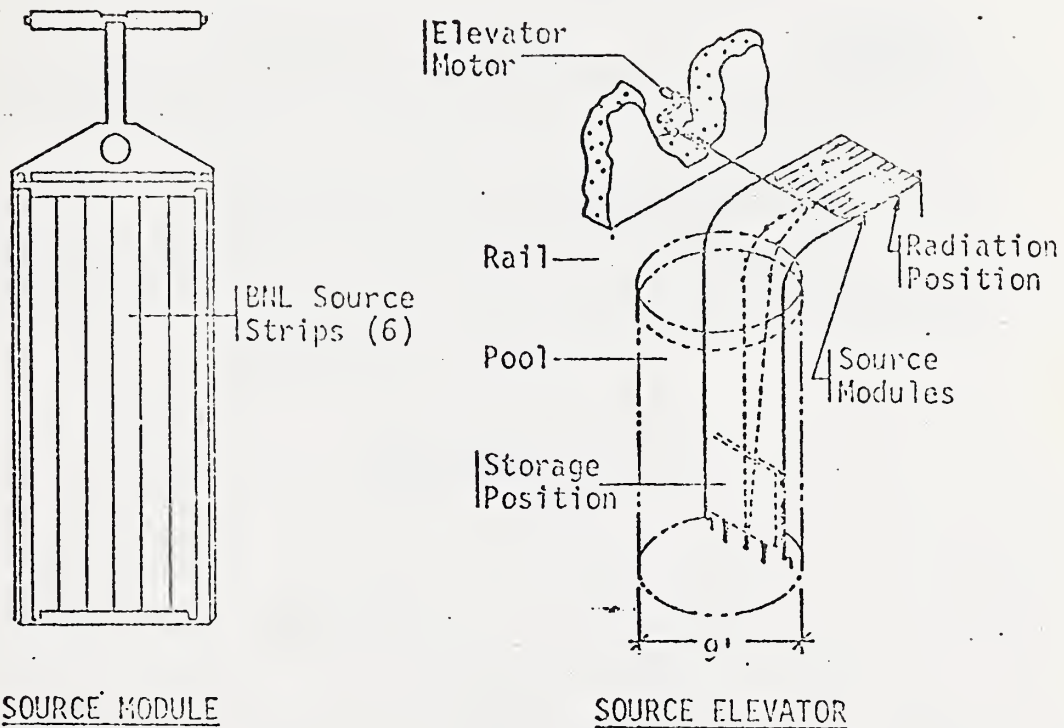
The processing system normally handles product packages placed inside of conveyor carriers. Up to 240 carriers can be processed per hour when each carrier load weighs less than 50 pounds. However, when carrier loads exceed 50 pounds but

are less than 100 pounds, longer package advance times decrease the maximum number of carriers which can be processed per hour. Maximum carrier dimensions are 42 inches long, 14 inches wide and 18 inches high.

The absorbed dose distribution in the HDI can be altered by changing: 1) the position and number of source modules (Fig. A-2) in the elevator, 2) source to package distance, 3) the step-dwell time cycle for the process conveyor and 4) the package shape and density. The HDI has the capability of delivering very uniform dose distributions in products such as papaya. The uniformity ratios (D_{max}/D_{min}) obtained in these studies were 1.22 or better. A complete treatise of the determination of these ratios is given in the Master File.

The HDI source consists of 8 modules, 12 inches long x 6 inches wide, each containing 6 BNL standard strips of cobalt-60 making a total of 48 strips (Fig. A-2). The dimensions of the active strips are 12.0 inches long, 0.64 inch wide and 0.06 inch thick, with specific activities of 80 to 90 Ci/gm. The total activity was approximately 214,000 curies in February 1967. Each cobalt strip was doubly encapsulated in stainless steel and leak tested after each encapsulation. The mean activity per module, measured at BNL on 2/1/67 was 27200 ± 25 curies with a maximum and

FIGURE 1



IRRADIATION CELL & CONTROL AREA

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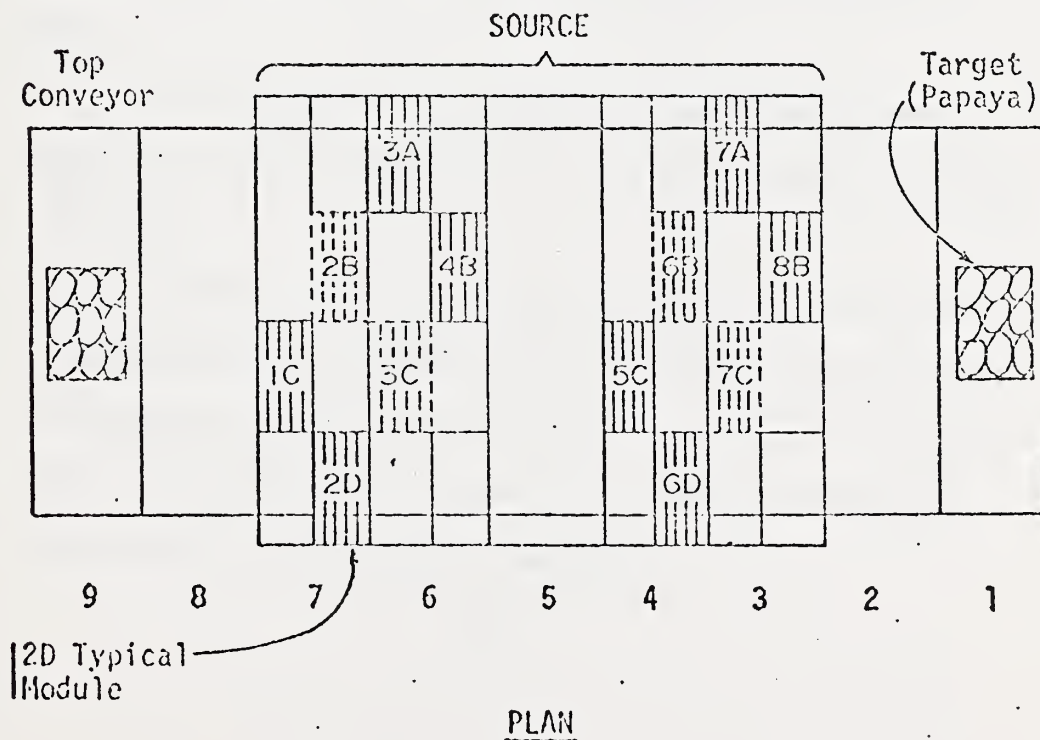
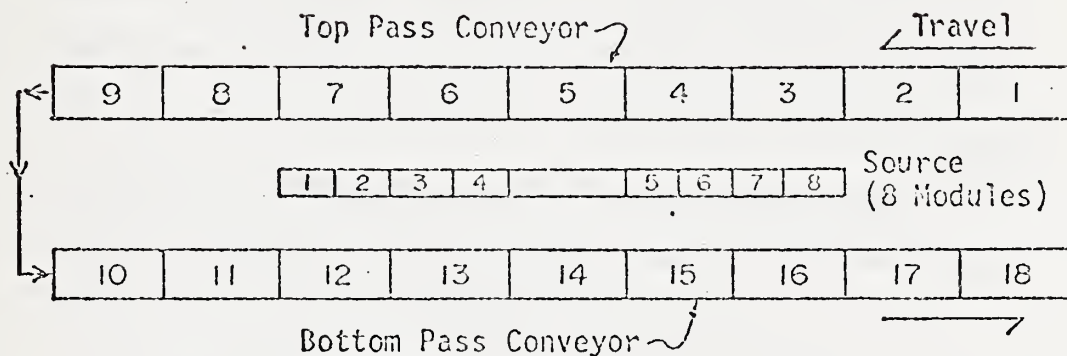
- A Control Area
- B Control Panels
- C Package Loading Station
- D Transfer Conveyor
- E Labyrinth
- F Product Carrier
- G Cell Pool
- H Source Elevator Drive
- I Water Circulation System
- J Laboratory

0' 50'

Approx. Scale

FIGURE 2

HAWAII DEVELOPMENT IRRADIATOR
TWO PASS SHUTTLE-DWELL SYSTEM



minimum activity of 27,300 curies and 27,100 curies, respectively,

5. Nature, Frequency and Accuracy of Dosimetry - Production System

When dose measurements are made inside of absorbing media, the dosimeter used must be satisfactory in size and shape and compatible in terms of density and atomic number with the medium in which it is to be used. If the dosimeter composition is similar to that of the absorbing medium, then it is assured that the spectral response of the dosimeter will match that of the medium (A-4).

Dosimeters used in food irradiation must be readily calibrated and consistent in response to absorbed dose. Dosimeters must be dose rate and energy independent in the desired range, reproducible, and capable of accurately assessing the absorbed dose, either by direct or indirect means.

In these studies, the Standard Fricke dosimeter and a modified extended range version of the Fricke dosimeter were used (A-5).

The Fricke method is generally accepted and widely used as an absorbed dose standard and is an ASTM standard method. The chemical reaction through conversion of ferrous ion to ferric ion by radiation is among one of the best known and researched of radio-chemical reactions.

The dosimeter is very nearly water equivalent and therefore excellent for the measurement of absorbed dose in fruits (papayas are 86.8 percent water).

All irradiator calibrations and control dosimetry in the papaya studies were conducted, using the two dosimetry systems mentioned above. The irradiator calibrations and characterization were conducted in three steps: 1) Location of maximum and minimum dose points, 2) Selection of operating parameters, 3) Measurement of absorbed dose at the maximum and minimum points.

1. Location of maximum and minimum dose points.

Upon commissioning of an irradiator system, general dose distribution studies are made to characterize the irradiator and to determine the location of the maximum and minimum dose regions in typical product packages, using the anticipated range of irradiator parameters such as source-to-target distance, product density, package size, dwell time, transit time, source activity and in the case of HDI, source module location.

2. Selection of Irradiator Parameters.

After completion of the preliminary dose distribution characterizations of 1 above, the most suitable operating parameters are selected for the intended effect.

3. Measurement of absorbed dose at maximum and minimum dose points.

In this step, accurate dose measurements are made through repeated measurement of the dose under actual production conditions.

The absorbed dose is determined inside of the packaged product at both the expected maximum and minimum dose points.

Once the irradiator has been calibrated and processing parameters established the process is controlled by monitoring the operating parameters. The parameters which are controlled are: 1) time cycle, 2) target position, 3) source position, 4) product density and size. Detailed data on calibration and process control methods for the Hawaii Development Irradiator are given in the Master File.

In this study, because operating parameters were changed frequently, an additional process control precaution was taken in that the dose was measured in typical packages of product in each run. This step is not necessary nor sufficient by itself for maintaining process control in commercial production.

6. References

- A-1 Oltmann, A. and O. A. Kuhl. "Fabrication of BNL Standard Cobalt-60 Source." BNL 848 (T-334), February 1964.
- A-2 Manowitz, B., "Isotopic Sources," Radiation Preservation of Foods, Publication 1973, NAS/NRC 1965.
- A-3 Harold J. Garber, S. A. Haram, A. L. Maharam, T. A. Vizzini, R. C. Wallace. HDI Preliminary Design Report, Nuclear Materials and Equipment Corporation, 3-1 to 8-16, Nov. 12, 1965.
- A-4 Weiss J. and F. X. Rizzo (1970) Chapter IX, pp. 232-260 in "Manual on Radiation Dosimetry," Edited by N. W. Holm and R. J. Berry, Marcel Dekker, Inc. N.Y.
- A-5 Dollar, A. M. and M. Hanaoka, unpublished procedure "Calibration and Process Control - Hawaii Development Irradiator", 1973.

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SECTION B: USE

1. Summary

Potential tephritid fly infestations, hazardous to fruit producing areas, are controlled by exposing commercial packages of fruit to gamma radiation energy at a minimum absorbed dose of 26 krad. Present USDA authorized quarantine treatments for fruit subject to infestation by various tephritid fly species of quarantine importance from Hawaii and other tropical and sub-tropical areas are not entirely satisfactory. A more efficient and wholesome treatment is needed to prevent the entry of fruit flies and the consequent economic losses to the continental United States. Exposure to gamma radiation provides a method superior to existing methods that either cause evident sensory changes in the fresh product, leave chemical residues, or are under challenge as to effectiveness.

The proposed treatment by gamma radiation will prevent the introduction of Oriental, Dacus dorsalis Hendel, Mediterranean, Ceratitidis capitata (Weidemann), and Melon, Dacus cucurbitae Coquillett, fruit flies to the continental U.S. A minimum absorbed dose of 26 krad of gamma radiation is established as that which meets the probit 9 level of quarantine security.

The recommended dose can be attained by controlling conveyor speed after the irradiator has been calibrated. Routine monitoring can supplement radiation dosimetry measurements to assure administration of recommended dose. The labeling requirements shall meet the specifications required by the Food and Drug Act.

Irradiated papayas probably will be consumed as part of the fresh fruit component of the diet. The effect of radiation on the dietary value of papayas is negligible. Desirable product qualities are not impaired by the treatment.

2. Purpose of Radiation

The purpose of treating papayas with ionizing radiation from either cobalt-60 or cesium-137 is to prevent the emergence of viable adults from irradiated tephritid fly egg and larval stages. The further intent is to use the treatment to prevent introduction of tephritid flies of quarantine importance found in Hawaii, into the continental United States. These fruit flies, the Oriental fruit fly, Dacus dorsalis Hendel, the Mediterranean fruit fly, Ceratitis capitata Wiedemann, and the melon fly, Dacus cucurbitae Coquillett, are frequently intercepted by quarantine inspectors at ports of entry to the continental United States (B-1).

Discovery of infestations of Mediterranean fruit fly in Florida and Texas required activation of expensive eradication programs in 1929, 1956, 1962, 1963, and 1966 (B-1).

Potential infestations (infested fruit) have been noted by quarantine inspectors (B-10). Improved quarantine treatment is the most effective means of assuring continued exclusion of these commercially important pests.

3. Justification of Need

The USDA has approved certain necessary quarantine treatments to prevent fruit fly introduction, establishment and consequent expensive control efforts, which may include significant insecticide consumption. At present, USDA approved quarantine treatments for fruit fly in fresh fruit or vegetable hosts require using either ethylene dibromide or methyl bromide as a fumigant or vapor heat using water-saturated, heated air (B-2). At present, approximately 80 percent of the papayas are treated by fumigation with ethylene dibromide. Fumigation treatment is based on a maximum permissible residue of less than 10 ppm of bromine calculated as inorganic bromide. The vapor heat treatment results in a product with slightly cooked characteristics, an altered texture and a loss of moisture.

Gamma radiation has been proposed as an effective treatment and one that is free of hazardous residues or undesirable quality changes in the treated product. The proposed treatment allows large-scale handling of papayas without altering market quality, sensory or nutritive values. Further, the proposed treatment produces no detectable chemical residues or chemical changes in the product at absorbed doses of radiation significantly greater than required to meet the established quarantine standards.

The economics of processing papayas favor locating production in a concentrated area, allowing processing through a centralized treatment unit. The proposed treatment incorporates improvements in the handling of the fruit from harvest to delivery by reducing delays inherent in the present treatment methods. The elimination of present delays will permit picking fruit at a more mature stage which will permit marketing a higher quality fruit or picking at the same degree of ripeness which would extend the shelf life of the fruit. Significant economics are possible because inspection and packaging can be completed before treatment.

4. Description of the Process

a. Dose Range

The proposed dose range is 26 krad to 75 krad. The evidence supporting this dose range is found in Section

C. The dose will be administered in a single treatment. The proposed minimum absorbed dose range of 26 to 75 krad will allow no more than 32 adults emerging from one million fruit fly larvae or eggs (Probit 9) with a 95 percent confidence. The maximum absorbed dose of 75 krad is well below the range where significant sensory or physical changes occur. The proposed dose which is based on biological variation among the species of fruit flies and their various life stages will allow the necessary latitude to provide a facility design that is economically feasible.

b. Recommendations for Proposed Use

Fresh market papaya will be irradiated under normal value judgement manufacturing and handling procedures. It is proposed to irradiate the papayas within their wholesale container. These containers are made of fiberboard and contain fruit cushioned or padded with other material. All packaging materials used will be fully approved for contact with food during irradiation in accordance with the Food Additive Regulations (B-3).

The design of the irradiation facility will be such that neither the papayas nor the containers are ever in contact with the radioactive material but are conveyed in a predetermined manner through the radiation field. Absorbed dose will be determined by measuring the dwell time required to obtain the dose desired. Although designs of commercial irradiators vary,

the basic principles remain the same.

The proposed treatment does not induce detectable chemical or sensory changes in any component of papaya.

Process control to be used in the proposed treatment are those generally recommended (B-5). These methods are summarized as follows:

- (1) A detailed and thorough calibration of the irradiator system upon commissioning, using acceptable dosimetry methods. The irradiator will be calibrated using the product as the test medium. In the calibration, the irradiation parameters will be those used in production.
- (2) After calibrations are completed, process control will be maintained by monitoring irradiator parameters and interpretation of the results, using standard statistical quality control techniques.
- (3) Inventory control will be maintained to assure that treated and untreated products are not mixed.

5. AEC Licensing Regulations Regarding Irradiator Facilities

While no specific irradiator design can be specified in this petition, the design, construction, and licensing of the irradiation facility to be used for food processing will be in accordance with current regulations enforced by AEC Licensing Regulations covered by Title 10, Chapter 7, Code of Federal Regulations entitled, "Rules and Regulations AEC," specifically, Parts 20, 30, and 71, or alternatively as required by the Agreement States which have assumed regulatory authority from the AEC under Part 150 of the above Chapter 7. Radiation facilities, fixed or mobile, not owned and operated by the Atomic Energy Commission are subject to the safety requirements outlined herein.

6. Proposed Regulation for USDA-APHIS Quarantine Treatment

The construction and use of the irradiation facility will be in accordance with current regulation in force by AEC licensing authority (CFR 10). Supervision by a Health Physicist will be provided as required.

§ 318.13-4f Administrative instructions approving gamma radiation treatment as a condition for movement of papaya from Hawaii.

- (a) Approved gamma radiation treatment. The Administrator of the Animal and Plant Health Inspection Service (APHIS) approves gamma radiation treatment, applied in accordance with the provisions of this section, as a treatment for papayas. Such fruits treated and handled as provided in this section may be certified for movement from Hawaii.
- (b) Prepacked papayas. Papayas prepacked for shipment using only materials approved in advance by the inspector may be treated by gamma radiation in a processing system approved for this purpose.
- (c) The fruit may be individually wrapped in approved packaging materials, placed alone or severally in cartons and sealed along the central flap with kraft paper tape. No additional covering or lining for the cartons is authorized.
- (d) Supervision of treatments and subsequent handling. The treatments approved in this section and the subsequent handling of the fruit so treated must be under the supervision of a plant quarantine inspector of the APHIS. Such treated fruits and

vegetables must be safeguarded against reinfestation during the period prior to movement from Hawaii in a manner satisfactory to the inspector. Certification of these commodities for such movement will be made only upon compliance with the prescribed treatment and post-treatment safeguards.

- (e) Department not responsible for damage. While the treatments approved in this section are judged from experimental tests to be safe for use with the designated fruits and vegetables, the Department of Agriculture and its inspector assume no responsibility for any loss or damage resulting from any treatment prescribed or supervised.

(f) Tolerance. Tests show that there is no detectable differences between untreated and treated papaya when treated as approved in this section.

7. Labeling

The labeling requirements shall meet the specifications described in CFR, Title 21, Chapter 1, Part 121, subpart G, paragraph 121.3003, for treatment of food with low dose gamma radiation (B-3). Hence, labels on all retail packages of irradiated papayas shall bear in addition to the other information required by the Food and Drug Act, the statement "Treated with ionizing energy" or "Treated with gamma energy." For all wholesale packages and on invoices or bills of lading of bulk shipments, the label statement should read "Treated with ionizing energy -- do not treat again," or "Treated with gamma energy -- do not treat again," in addition to the other information required by the Act.

8. Impact on Consumer's Diet

The primary value of papaya in food is as a rich source of ascorbic acid (540/mg/100 g dry matter) (Table B-1). The relative concentration of ascorbic acid is not affected by radiation doses is more than tenfold greater than the minimum proposed for disinfestation (300 Krad).

Table B-1

COMPOSITION OF PAPAYA PER 100 grams EDIBLE PORTION

% Moisture	86.80	grams
Food Energy	46.00	calories
Protein	0.39	g
Fat	0.06	g
Total Carbohydrate	12.18	g
Fiber	0.58	g
Ash	0.57	g
Calcium	29.90	mg
Phosphorus	11.60	mg
Iron	0.19	mg
Thiamine	0.03	mg
Riboflavin	0.04	mg
Niacin	0.33	mg
Reduced Ascorbic Acid	363.00	mg)
)
Total Ascorbic Acid	540.00	mg)
)
Reducing Sugar	77.20	mg)
)
Carotenoids (as B-carotene)	17.30	mg)

References B-4 (p. 86), B-6

The only effect of low dose radiation, less than 150 krad, is to delay softening, also referred to as delayed ripening which can slightly extend market shelf-life. There are no significant changes in appearance or sensory attributes (B-4).

Approximately 13,045,000 pounds of whole papaya were marketed for fresh consumption within the State of Hawaii, during 1970 (B-6). The de facto population at the end of the year 1970 was estimated at 781,963 persons (B-7). Disregarding papaya exported as gifts, the per capita consumption was 17 pounds per year. Allowing for the non-edible portion, this per capita consumption is equivalent to 12 pounds of papaya per year, or 15 grams (1.8 grams dry fruit solids) per person per day (B-8). Assuming a four calorie per gram energy equivalent, the per capita consumption would average almost eight calories per day. For a daily requirement of 3,000 calories, the average consumption of papayas in Hawaii is less than 0.23 percent of the total calorie requirement.

Out-shipments of papaya from Hawaii is nearly 10 million pounds annually which is distributed to mainland markets, serving a population of slightly more than 150 million people (Table B-2). Because of the cost of papayas in relation to other foods in the mainland markets, it is highly unlikely that per capita consumption in mainland markets will exceed that of Hawaii.

It is expected that papaya consumed in Hawaii will not be irradiated. The present annual per capita consumption of papayas in the West Coast of the U.S. is nearly 1/3 pound which is less than 2 percent of that in Hawaii.

TABLE B-2

PAPAYA PRODUCTION AND MARKETING¹

Year	Total Production (1000 lbs.)	Out- shipments (1000 lbs.)	Local Fresh Other Use (1000 lbs.)	Average Bearing Acres	Yield Per Bearing Acre (1000 lbs.)	Percent Production Exported	Per Capita	
							Consumption Local 2 (lbs.)	Consumption West Coast
1961	15,760	2738	11218	570	27.7	17.3	18.5	
1962	14,705	3320	10157	540	26.3	22.5	16.1	
1963	14,100	3196	8529	460	30.7	22.6	13.1	
1964	24,915	4436	13178	750	33.2	17.8	19.6	
1965	19,380	4939	9759	790	24.5	25.4	14.0	
1966	18,680	5308	9917	600	31.1	28.4	13.9	
1967	22,845	7224	12169	760	30.1	31.6	16.4	
1968	23,550	7876	12209	830	28.4	33.4	15.4	0.3
1969	19,235	6032	10305	850	22.6	31.3	15.0	0.3
1970	24,960	10893	13045	1040	24.0	44.0	16.7	0.6
1975 ³	29,570	16570	13000	1200	25.4	56	16	0.5
1985 ³	72,270	58270	14000	2800	25.8	79	16	1.3

* Basis of marketing 60 percent of export papaya in an assumed West Coast target population of 18 in 1968, 18.5 in 1969, 19 in 1970, 21 in 1975, and 28 millions in 1985.

- Sources: 1. Department of Agriculture, Statistics of Hawaiian Agriculture, USDA-SRS (B-7)
 2. Department of Planning and Economic Development, Resident Population of Hawaii, Table 3, P. 3 in The State of Hawaii Data Book, Honolulu, Hawaii, 1968 (B-2) 8
 3. Table 4 Disinfestation of Fruit by Irradiation, IAEA, 1971 (B-9)

9. References

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SECTION C: TECHNICAL EFFECT

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SECTION C: TECHNICAL EFFECT

1. Summary

Treatment of papaya by gamma radiation from cobalt-60 or cesium-137 at an absorbed dose of not less than 26 krad will prevent the emergence of adult flies from irradiated egg or larval stages of 3 species of tephritid flies:

Dacus dorsalis, D. cucurbitae, Ceratitidis capitata.

that
Studies have established/treatment at a maximum absorbed dose of 75 krad will allow commercially feasible operations and will not induce physical or sensory changes in the fruit and will meet the required level of quarantine security.

The treatment can be applied to papaya in all stages of maturity or ripeness without altering desirable physical, nutritional or sensory quality attributes or market shelf-life and meet the security requirements deemed necessary by USDA to protect U.S. mainland from economic losses from the above three species of fruit flies.

The approved treatment would be applied to papayas, packaged in FDA approved materials, in such a manner as to prevent reinfestation of fruit destined for shipment to areas quarantined against these three species of fruit flies, specifically the continental United States.

Detailed data on the effectiveness of disinfestation treatment of papaya are provided in a series of reports by the University of Hawaii, College of Tropical Agriculture, Hawaii Development Irradiator, and the USDA-ARS Fruit Fly Investigation Laboratory.

2. Analysis and Interpretation of Data

Three species of tephritid flies of quarantine importance are found in Hawaii, these are: Oriental fruit fly, Dacus dorsalis Hendel, the Mediterranean fruit fly, Ceratitidis capitata Wiedemann, and the melon fly D. cucurbitae Coquillett. Specimens of one or more of these three species are frequently found in shipments of fumigated or vapor-heat treated fruit from Hawaii and elsewhere, at continental United States ports. The present quarantine treatments and inspection efforts are less than completely effective and the Mediterranean fruit fly had to be eradicated from the continental United States in 1929, 1956, 1962, 1963, and 1966 with much effort and expense (C-1).

The level of security adopted by USDA for quarantine treatment of commodities that have a significant pest risk is referred to as probit-9 which is equivalent to 32 survivors from a population of 1 million (C-1). Research studies have demonstrated that gamma radiation at doses of 26 krad provides the

requisite degree of security for papaya infested with any of the three species of fruit fly (C-2). This is the only technical effect claimed in this petition.

The three species of fruit flies found in Hawaii, deposit eggs in papayas and other fruits. Survival and rates of development of fruit flies depends on temperature in the range 30-110° F. (16.7 to 56°C.) The optimum range for development of fruit fly in fruit is about 70-85° F. (40 - 47°), a condition prevailing in many of the fruit fly free areas of the continental U.S. and in which host fruit is grown. Eggs hatch in 2 to 4 days and larvae feed on the fruit for 6-10 days. When mature, the larvae leave the fruit, normally dropping to the soil where they pupate. Adults emerge from the pupae in 9-12 days, completing the life cycle. There are no physiological resting stages in the development of these three species of fruit flies, and large populations can develop from a single clutch of eggs each month. The eggs and larvae are of primary quarantine importance, since they may be within the fruit being shipped from infested to noninfested areas.

Preliminary Studies

The primary concern of the proposed treatment is to prevent fertile adult fruit flies from being shipped into noninfested areas. In developing the proposed treatment, the sensitivity of

fruit fly eggs, larvae or pupae at different ages to gamma radiation was determined. The basis for survival was hatch of eggs, pupation of larvae and emergence of adults. Emergence of adults involves breaking the puparium at the eclosional suture, as well as partial or complete emergence of the flies.

The data were subjected to logit analysis and the dose required to effect an inhibition of adult emergence equivalent to 99.9968 percent ($=32/1,000,000 = \text{probit } 9 - \text{logit } 10.34974$) were calculated for each of the three species for each life stage-age (egg, larvae and pupae of different ages) observed (C-3 and C-7). Because of limitations in computer technology, these data were not subjected to the most appropriate statistical treatment (e.g. natural mortality applicable to each dose could not be used and an average natural mortality was used for each stage -age observed). To facilitate easy comparisons of these preliminary data with subsequent data, the dose was converted from Roentgens (88 ergs/gr. of air) to rads (100 ergs/gr. of air) (C-4) and subjected to probit analysis using natural mortalities appropriate to each dose (C-5). These probit analyses are discussed in an unpublished report (C-6) and the results are summarized in Table C-1. Significant log-probit regression lines were obtained for all larval ages observed for all three species (28 regression lines). The doses required to effect an inhibition

of emergence of 99.9968 percent (probit 9) and their 95 percent of fiducial (confidence) limits were calculated. The upper 95 percent of fiducial limits about the dose that will produce 99.9968 percent inhibition of adult emergence were all less than 26 krad except for two lines (Table C-1). For these two lines, it appears that variation inherent in conducting such tests as well as variability in susceptibility of the flies themselves, gave predicted doses considerably above those of other stages for the same species of fruit fly. These results, however, can be extended to expected operating conditions only with caution for exposure was to naked eggs, larvae and pupae, and doses were measured in terms of roentgens irradiated rather than rads absorbed (conversion from one unit to the other by simple multiplication requires several assumptions that may be inappropriate).

The survival of these three species of fruit flies in papayas and other fruits was determined when exposed to doses of gamma radiation ranging from 1 to 40 kR. In these studies 2,600 papayas were treated in a 416 Ci cobalt-60 (1957) source. Before treatment, the fruit were exposed to populations of about 100,000 adult fruit flies of the three species in outdoor cages to achieve a high level of infestation. The papayas had been picked mature green when heavy infestations would be unlikely.

TABLE C-1

Calculated Dose of Gamma Irridation (Kilorads*) Required to Prevent 50 percent (Probit 5) and 99.9968 percent (Probit 9) Emergence of Adults.

Oriental Fruit Fly--Dacus dosalis

Stage and age irradiated	95 Percent Confidence Interval			
	Probit 5		Probit 9	
	Upper Kilorads	Lower Kilorads	Upper Kilorads	Lower Kilorads
Eggs - 25 hours	1.75	1.29	10.88	3.17
Larvae age - 1 day	1.83	1.69	5.17	3.80
2 days	1.69	1.57	4.50	3.50
3	2.00	1.69	5.95	3.06
4	2.30	1.74	21.07	4.47
5	-	-	-	-
+ water* 5	-	-	-	-
6	2.51	2.30	5.94	3.79
+ water* 6	4.63	2.44	29.80	7.63
Fully developed	3.64	3.31	15.20	9.80
Broken pupae	4.03	3.56	20.55	10.90

Mediterranean fruit fly--Ceratitls capitata

Eggs - 45 hours	1.71	1.03	38.00	2.43
Larvae age - 1 day	1.55	0.04	3.4 x 10 ¹⁰	1.82
2	1.49	1.10	8.86	2.10
3	1.51	1.32	4.70	2.80
4	-	-	-	-
+ water 5	-	-	-	-
5	1.61	1.53	4.45	3.70
+ water 6	3.13	2.08	12.32	5.24
6	1.70	1.58	4.17	3.17
Fully developed	-	-	-	-
Broken pupae	2.41	2.07	9.97	5.73

Melon Fly--Dacus cucurbitae

Eggs - 21 hours	2.61	2.24	8.84	3.71
Larvae age - 1 day	3.37	2.31	87.62	5.32
2	2.82	2.43	16.08	6.36
3	3.18	2.66	13.94	6.24
4	3.37	2.98	9.82	5.60
+ water 5	6.00	4.96	12.90	9.22
5	3.69	0.83	1.92 x 10 ⁶	4.02
+ water 6	-	-	-	-
6	-	-	-	-
Fully developed	3.59	2.69	41.34	12.21
Broken pupae	4.10	3.53	20.91	10.75

*Sufficient water added to cover larvae. Normally media was only moist at this time with larvae fully exposed.

The natural infestation in Hawaii is predominately by the oriental fruit fly. Before treatment, the infested fruit were randomly divided into five equal sized lots. One lot was held without further treatment as a control while the other four lots were exposed for different lengths of time to gamma irradiation from the 416 Ci cobalt-60 source.

In the original publication (C-7) the doses of gamma irradiation required to effect a probit 9 inhibition of adult emergence from infested fruit were estimated, using eye-fitted log-probit regression lines, at between 21 and 28 kR for fruit infested with oriental fruit fly and 15.6 kR for fruit infested with melon fly (Tables C-2). Complete inhibition of adult emergence of the Mediterranean fruit fly occurred at all doses administered (2.5 to 40.0 kR).

The primary purpose of using doses that produce effects less than that desired is to aid in predicting that dose which will just produce the desired effect. To verify that the predicted dose does, in fact, produce the desired effect (a 99.9968 percent inhibition of adult emergence from fruit infested by Dacus dorsalis, Dacus cucurbitae, or Ceratitis capitata) it is necessary to conduct tests using the predicted dose under conditions expected during normal operations.

TABLE C-2

(a)

Gamma Radiation Required to Prevent Emergence of Adult
Fruit Flies from Treated Fruits and Vegetables (Ref. C-7)

<u>Fruit fly species</u>	<u>Fruit</u>	<u>No. Fruit_b Flies</u>	<u>Dosage (kR) Prevent Emergence (a)</u>
Oriental	Papaya	143,000	20.6
	Avocado	27,000	21.9
	Misc. fruit ^c	55,000	28.0
Melon	Misc. fruit ^d	44,000	15.6
Mediterranean	Papaya	40,000	e

a Less than 32 per 1 million will develop to adult stage.

b Estimated from number of pupae recovered from controls.

c Includes litchi, Barbados cherry, hog plum, ball kamani, tangerine, yellow guava, strawberry guava, Terminalia sp.

d Includes papaya, tomato, cucumber.

e Complete mortality at all dosages tested 2.5-40.0 kR.

4. Commercial Scale Studies

These studies were conducted with the HDI located at Hawaii and a summary of the results have been published by Seo et al. (C-9).

The natural infestation of off-grade Solo papaya was enhanced by exposing fruits in cages containing populations of fruit flies. The 270 ft.³ infestation cages contained approximately 50,000 sexually mature adults each of the tephritids known as oriental, Dacus dorsalis, Hendel, melon, D. cucurbitae Coquillett, and Mediterranean, Ceratitis capitata Wiedemann. Each fruit weighed about 1 to 2 lbs. The maturity of the fruits varied from color-breaking to 1/3 colored. After 2.5 days of exposure, the infested fruits were removed from the cages. Decayed fruits were discarded and the remaining fruit placed in field boxes. The field boxes were then vacuumed to remove the adults before moving the fruits into the insectary.

In the insectary, the papayas were vacuumed again if any adult was found. Invaginated glass traps, containing diluted guava juice or tomato juice were hung throughout the insectary to catch adults that escaped during the vacuuming. A sample, approximately 25 percent of the infested fruits/^{was} used to estimate the population of eggs and larvae that would develop and emerge as adults in the untreated fruit. The remaining 80-367 fruits were packed upright in

cartons for irradiation in HDI.

The bulk density of each irradiated carton was calculated from the weight and volume of the carton. The absorbed dose was determined using the methods described on page A-7 (see also reference A-5).

The cartons, made from double-faced corrugated fiber board, had outside dimensions of 10.75" x 14.5" x 6.25". The bottom flaps of each carton were stapled closed and each carton was lined with single-faced corrugated fiberboard. A 13.875" x 5.625" fiberboard liner was placed on the bottom of the carton to cushion the pedicel of the papaya. Additional liners were used to hold the fruit firmly in place when necessary. The top flaps of the fruit filled boxes were sealed with 2" wide gummed kraft paper tape.

Although entry of the sealed cartons by adult fruit flies would be nearly impossible, the cartons were wrapped in a tarpaulin during 40 minutes of transportation between the insectary and HDI. In the insectary, the irradiated papayas were removed from the cartons and placed on fruit trays in fruit-holding boxes, containing approximately 1.74 pounds of air-dried sand. The papaya were cut along one surface and the cut surface placed on the sand to remove free water and to lessen natural larval mortality. The stacks of

fruit-holding boxes, containing irradiated fruits remained isolated from those containing the unirradiated fruits.

Reinfestation of the fruits by adults that had emerged from the irradiated fruit was minimized by daily trapping and by using sponge rubber sealing between each box in the stack.

Collecting of pupae and mature larvae from the unirradiated and irradiated papayas was completed after 3 weeks and 5 weeks, respectively. On the final week, the living mature larvae and pupae were extracted from all decayed fruit. To avoid contamination, pupae and larvae from irradiated and unirradiated fruits were counted and held in air-dried sand in separate cages until the adults emerged from the puparia at ambient temperatures of 50-87° F. Then the adults were counted and the population in the irradiated fruits was assumed to be the product of the number of adults obtained from the unirradiated fruits adjusted by the ratio of number of irradiated fruits to the number of unirradiated fruits.

The required level of security is met by treating papaya at a minimum absorbed dose of 25.5 krad in insect proof commercial packages of a bulk density of up to 26 lb./ft.³, under normal atmospheric conditions and at prevailing ambient temperature (Table C-5). Data supporting this recommended dose were published by Seo et al., C-5.

5. Results of Commercial Scale Studies

All survival data are tabulated in order of minimum absorbed dose as measured by Fricke dosimetry. The tables follow:

TABLE C-3

Survival of Dacus dorsalis (Oriental fruit fly)
in infested papayas treated by gamma radiation

Date Treated	No. (1) Fruit	No. Ctn.	Bulk Density	Radiation Observed Dose*		Survivors (2)		Survivors (3)
				Min.	Mix.	Untreated Fruits Pupae	Adult	Treated Fruits Adult
10/17/67	120	10	23.8 ± 0.2	20.4	25.7	6,994	5,446	1
9/1/67	132	11	24.8 ± 0.2	21.0	25.6	5,027	4,605	1
9/12/67	108	9	26.2 ± 0.3	21.6	26.6	32,858	27,009	0
8/22/67	86		25.0 ± 0.0	22.0	26.8	14,945	12,851	2
9/6/67	148	12	24.3 ± 0.2	22.2	26.6	3,079	2,418	0
9/22/67	155	13	21.5 ± 0.2	22.3	28.8	19,582	15,795	0
10/24/67	96	8	24.0 ± 0.5	22.6	28.7	17,709	14,045	0
9/8/67	130		22.0 ± 0.2	23.1	26.9	17,075	9,959	0
9/19/67	144	12	21.9 ± 1.3	23.1	29.3	15,004	12,489	0
9/15/67	120	10	23.9 ± 0.3	23.3	28.8	18,195	15,766	0
8/29/67	113	13	26.3 ± 0.6	23.8	29.6	16,199	12,152	0
2/20/67	207	14	24.5 ± 0.1	24.2	30.3	50,322	39,252	1
12/12/67	60	5	25.3 ± 0.3	24.3	30.3	7,823	2,906	0
3/19/68	165	16	21.4 ± 0.1	24.6	28.7	66,768	51,166	0
3/22/68	161	16	21.4 ± 0.1	24.7	29.2	11,538	8,439	0
2/13/68	248	16	26.0 ± 0.3	24.7	31.1	37,310	32,756	0
4/2/68	266	17	21.4 ± 0.1	24.8	37.4	17,738	11,627	0
2/6/68	123	10	23.7 ± 0.1	25.0	31.0	2,232	1,917	0
2/9/68	262	16	26.9 ± 0.2	25.4	31.7	18,503	16,191	16
1/26/68	183	14	22.7 ± 0.2	25.5	30.6	49,597	45,074	0
1/30/68	294	15	22.9 ± 0.2	25.9	30.9	65,836	55,530	0
11/7/67	156	13	23.6 ± 0.2	25.9	36.9	19,741	13,290	0
2/16/68	224	15	22.3 ± 0.1	26.2	30.9	35,195	30,649	0
11/28/67	132	11	25.7 ± 0.1	28.1	35.5	13,819	7,254	0
11/14/67	144	12	24.8 ± 0.6	28.6	35.2	21,148	14,275	0
12/5/67	108	9	26.3 ± 0.1	28.6	35.0	27,395	18,393	0
12/1/67	72	6	26.6 ± 0.3	28.8	35.5	4,173	975	0
10/20/67	144	12	23.1 ± 0.6	29.8	37.8	15,525	13,574	0
Total				(20.4 - 37.8)		631,330	495,803	21

* Absorbed dose (krad) by in-place Fricke dosimeters

- (1) Number of fruit exposed to fruit fly infestation subjected to treatment.
- (2) Number of pupae and adults recovered from untreated control fruit.
- (3) Number of pupae and adults recovered from treated fruit.

TABLE C-4

Survival of Ceratitis capitata (Mediterranean fruit fly)
in infested papayas treated by gamma radiation

Rate Treated	No. (1) Fruit	No. Ctn.	Bulk Density	Radiation Observed Dose*		Survivors (2) Untreated Fruits		Survivors (3)
				Min.	Max.	Pupae	Adult	Treated Fruits Adult
10/17/67	120	10	23.8 \pm 0.2	20.4	25.7	9,512	6,505	1
9/12/67	120	10	26.2 \pm 0.3	21.6	26.6	41,512	30,584	0
8/22/67	94		25.0 \pm 0.0	22.0	26.8	7,687	5,120	0
9/22/67	120	10	21.5 \pm 0.2	22.3	28.8	35,379	25,701	0
10/24/67	60	5	24.2 \pm 0.2	22.6	28.7	21,229	14,032	0
9/19/67	132	11	21.9 \pm 1.3	23.1	29.3	21,216	13,388	1
9/15/67	120	10	23.9 \pm 0.3	23.3	28.8	44,665	29,052	0
8/29/67	116	13	26.3 \pm 0.6	23.8	29.6	14,842	10,501	0
11/7/67	108	9	23.6 \pm 0.2	25.9	36.9	15,089	10,874	0
11/14/67	96	2	24.8 \pm 0.6	28.6	35.2	40,023	25,311	0
12/1/67	96	8	26.6 \pm 0.3	28.8	35.5	9,835	6,295	0
10/20/67	108	9	23.1 \pm 0.6	29.8	37.8	8,760	6,153	0
Total				(20.4 to 37.8)		236,749	183,516	2

*Absorbed dose (krad) by in-place Fricke Dosimeters

- (1) Number of fruit exposed to fruit fly infestation subjected to treatment.
- (2) Number of pupae and adults recovered from untreated control fruit.
- (3) Number of pupae and adults recovered from treated fruit.

TABLE C-5

Survival of Dacus circurbitae (Melon fly)
in infested papayas treated by gamma radiation

<u>Date Treated</u>	<u>No. (1) Fruit</u>	<u>No Ctn.</u>	<u>Bulk Density</u>	<u>Radiation Observed Dose*</u>		<u>Survivors (2) Untreated Fruits</u>		<u>Survivors (3) Untreated Fruits</u>	
				<u>Min.</u>	<u>Max.</u>	<u>Pupae</u>	<u>Adult</u>	<u>Adult</u>	<u>Adult</u>
9/1/67	132	11	24.8 + 0.2	21.0	25.6	6,844	4,268	0	0
8/22/67	98	8	25.0 + 0.0	22.0	26.8	574	312	0	0
9/6/67	128	11	24.3 + 0.2	22.2	26.9	13,416	6,461	0	0
9/8/67	129	10	22.0 + 0.2	23.1	26.9	2,388	1,719	0	0
9/15/67	108	9	23.9 + 0.3	23.3	28.8	583	313	0	0
8/29/67	112	13	26.3 + 0.3	23.8	29.6	9,011	3,436	0	0
Total				(21.0 to	29.6)	32,816	16,509	0	0

*Absorbed dose (krad) by in-place Fricke Dosimeters

- (1) Number of fruit exposed to fruit fly infestation subjected to treatment.
 (2) Number of pupae and adults recovered from untreated control fruit.
 (3) Number of pupae and adults recovered from treated fruit.

6. Absence of Tephritid Fruit Flies in Large-scale Shipping Studies

More than 540 cartons containing 5,000 treated fruit included in simulated and large-scale shipping studies were examined. No fruit fly or other infestations were noted in any cartons containing treated papaya. Assuming the natural level of infestation was less than 10 per fruit then the potential number of survivors would be only 50,000. On the basis of probit-9 security, no surviving fruit flies would have been expected in a sample of this size.

Twenty one adult Dacus dorsalis, the least susceptible of the three species of fruit flies to gamma irradiation, emerged from papayas that had absorbed between 20.4 and 37.8 krad, while 495,803 adults emerged from the untreated fruit (Table C-3). The irradiated and unirradiated papayas contained egg and larval stages of varying ages. Assuming that the irradiated and unirradiated fruit contained the same number of fruit flies and that the natural mortality factor affected both populations equally, the inhibition of adult emergence as a result of exposure to 20.4 to 37.8 krad of gamma irradiation was 99.9958 percent which did not differ significantly from the 99.9968 percent specified by USDA for quarantine purposes. Adult emergence of Dacus cucurbitae and Ceratitis capitata were less than that of Dacus dosalis (Tables C-4 and C-5). Thus, the desired level of inhibition of adult emergence necessary to affect the specified quarantine security can be achieved for these three species of fruit flies by exposing infested fruit to 22.8 krad (geometric mean of 37.8 and 20.4).

7. Effect of Process on Nutritive Content and Sensory Qualities

There are no significant differences in aroma and flavor between fumigated controls and papaya fruit irradiated at minimum absorbed doses in the range 25-100 krad. Texture differences were observed in which irradiated fruit was rated as firmer than that of the fumigated. A significant difference ($p=0.05$) was also observed in flesh color of the fruits, i.e., irradiated fruits were rated as having a more desirable flesh color than fumigated fruits. These differences are believed to relate to delayed ripening of irradiated samples (C-2; pp. 214, 227).

Sensory data from taste panels in California were compared with those obtained in Hawaii, using samples of identical lots of papayas, which had been either hot-water treated and fumigated or hot-water treated and irradiated. The fruit were air freighted from Hawaii to the University of California at Davis, for evaluation at the same time as fruit were being evaluated in Hawaii. These studies were designed to evaluate acceptance of papaya by people of varying degrees of familiarity from different localities. Although this consumer group variability could lead to different responses to an irradiated product (C-9; pp. 51) the test panels could

detect no major differences in the quality of the papayas (C-2; pp. 166, 167, 190, 213).

In subsequent simulated shipping studies, few significant differences were found in the sensory scores of absolute control, fumigated, vapor-heat treated and irradiated (minimum absorbed dose of 25, 50, 75, 100, 150 krad) fruit. The vapor-heat treatment resulted in a significantly lower aroma score in some lots while irradiation at 25 krad resulted in significantly higher aroma and flavor scores in half of the lots. In no instance were the irradiated papaya (25, 50, 75, 100, 150 krad) scored lower than the absolute controls, fumigated or vapor-heat treated fruit (C-2; pp. 167, 190).

In controlled large-scale shipping studies to California, where fumigated and vapor-heat treated papaya were compared with those irradiated at 25 and 75 krad, the only significant difference was in color score. The mean color score for 75 krad treated fruits was significantly ($p=0.05$) higher when compared with all other treatments. There were no significant differences in aroma, flavor, or texture among these treatments (C-2; pp. 214, 227 and 230).

Chemical and physical analyses for fruit picked at three preharvest color stages: color-turning, 1/4 colored and 3/4 colored. There were no significant differences

attributable to radiation treatment in any chemical parameter (C-2, pp. 116 and C-9, pp. 51).

Total soluble solids: There were significant differences ($p=.01$) in total soluble solids attributable to initial ripeness; values for riper fruits were higher (C-2; pp. 95).

Dry matter: There were no significant differences in dry matter content within comparisons (harvest date, hot-water treatment, radiation dose and length of storage). More than two-thirds of the dry matter is reducing sugar (C-2; pp. 95, 107, 113 and 117).

Total sugar (as invert sugar): There were no increases in total sugar as measured by an increase after acid hydrolysis.

Reducing sugar: There were no significant differences in reducing sugar (10-11 percent of the fresh weight of papaya pulp) regardless of treatment or color development stage, once at the mature harvest stage.

There were significant differences ($p=0.01$) attributable to seasonal difference when compared on the basis of harvest date (C-2; pp. 100, 116).

Total ascorbic acid: There were significant increases which related to advancing preharvest color development ($p=0.01$), irradiation at 125 krad ($p=0.01$), hot-water treatment ($p=0.05$) and different harvest dates ($p=0.05$) (C-2; pp. 98, 99).

Reduced ascorbic acid: There were significant differences which paralleled results for total soluble solids within comparisons (C-2; pp. 96, 97).

Reduced ascorbic acid was not affected significantly unless papaya were treated by gamma radiation at minimum absorbed doses in excess of 25 - 250 krad. The amount of reduced ascorbic acid in papaya is constant at $67.3 \pm 0.7\%$ of total ascorbic acid.

(See Table B-1 for composition of papaya.)

Carotenoids:

Increases in carotenoid values parallel advancing color development (C-2; pp. 101, 128).

Physical tests: Both the Durometer method and the

Magness-Taylor method showed significantly ($p=0.01$) higher values when irradiated samples were compared to controls from the

same harvest lot, indicating firmer fruit in the irradiated lot (Reg C-2; pp. 101, 124, 125).

8. Effect of Process on Shelf-Life and Marketability

The mean number of days marketable was derived from frequency tables which present the number of marketable fruit for each day of the inspection cycle (C-2; pp. 170 - 173). The mean was calculated using the grouped data. Because of series to series variation a pooled mean would not be truly representative of the population, hence each series was considered individually.

The first series (harvested 4/30/69 - Ref. C-2, p. 162) was devised to represent both a short and long distribution storage period, i.e., air transport five days storage and surface transport seven days storage. In the latter case the extra two days of refrigeration added only one-half to one day to the total shelf-life. Possibly the higher humidity conditions prevailing in the laboratory storage facility favored decay and softening. These conditions are not a normal feature of commercial handling and were adjusted for in subsequent storage cycles.

The market-life of vapor-heat treated fruit of this series was one to two days longer (significant at $p=.01$) than any other treatment for the air equivalent series and better than the fumigated lot or lot irradiated at a minimum absorbed dose of 50 krad. This difference in marketable quality of the

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TABLE C-1

SUMMARY OF SHELF-LIFE DATA

	<u>Fumigated</u>	<u>Pooled Data</u>	<u>Irradiated 25 krad</u>
Mean days marketable by treatment all series	12.97 \pm 0.23 (N=430)	14.04 \pm 0.18 (N=860)	15.10 \pm 0.26 (N=430)
Mean days to discard- softness - grade 2	14.08 \pm 0.34 (N=227)	14.59 \pm 0.31 (N=332)	15.68 \pm 0.65 (N=105)
Mean days to discard- decay - grade 3	11.73 \pm 0.28 (N=203)	13.69 \pm 0.21 (N=528)	14.90 \pm 0.28 (N=325)
Mean days marketable by series harvest dates			
4/30/69 Air Equivalent		9.71 \pm 0.17 (N=202)	
4/30/69 Surface Equivalent		11.63 \pm 0.18 (N=158)	
6/17/69 Air Equivalent		14.37 \pm 0.34 (N=261)	
8/4/69 Surface Equivalent		18.92 \pm 0.25 (N=239)	

All comparisons between treatments and harvest date series are significantly different (p=.01).

vapor-heat treated lot could be attributed to drying during treatment which would reduce free moisture, thus inhibiting or limiting mold development, although the treatment caused significantly lower aroma scores and loss in weight.

No shelf-life comparison with absolute controls was possible for the first series because an insufficient number of samples remained after the initial seven days of storage. In the later two series (harvest dates 6/17/69 and 8/4/69) the market-life for controls was significantly poorer than all other treatments except for the fumigated lot in the second series.

The shelf-life of irradiated lots of all series was generally significantly better than all other treatments (Table C-6). No difference could be attributed to different radiation doses in the range 25 - 150 krad.

9. Induced Radioactivity

All packaging materials shall have been USFDA approved. Such material will have been demonstrated to be free of induced radioactivity (C-10). Under the conditions of the proposed system the treated fruit also will be free of induced radioactivity since no induced radioactivity results from exposure to energies of less than 2.2 Mev (C-11).

10. References

- C-1 See Reference B-1
- C-2 Hawaii State Department of Agriculture, Hawaii Food Irradiation Program, NVO 374-17 (Vol. 1) 1970.
See Reference II-3
- C-3 Burditt, A. K. Jr., S. T. Seo, Dose Requirements for Quarantine Treatment of Fruit Flies with Gamma Radiation. Disinfestation of Fruit by Irradiation, pp. 33-41, IAEA Vienna (1971).
- C-4 Hamer, David E., and David S. Ballantine, Radiation Processing, Chemical Engineering, April 19, 1971; pages 98-__
- C-5 Daum, R. J., A. K. Burditt, Jr., A Reexamination of Dose Requirements for Quarantine Treatment of Fruit Flies with Gamma Irradiation. Unpublished report June 1974.
- C-6 Daum, R. J., Revision of Two Computer Programs for Probit Analysis. Bulletin Entomological Society America., 16(1): 10-15, March 1970.
- C-7 Balock, J. W., A. K. Burditt, Jr., S. T. Seo, E. K. Akamine, Gamma Radiation as a Quarantine Treatment for Hawaiian Fruit Flies, J. Econ. Entomology, 59, pp. 202-204 (1966).
- C-8 Seo, S. T., Kobayashi, R. M. Steiner, L. F., Chambers, D. L. Dollar, A. M., and Hanaoka, M., Hawaiian Fruit Flies in Papaya, Bell Pepper, and Eggplant: Quarantine Treatment with Gamma Irradiation, J. Econ. Entomology, pp. 937-939 (1973).
- C-9 Moy, J. H., E. K. Akamine, J. L. Brewbaker, I. W. Buddenhagen, E. Ross, H. Spielmann, M. D. Upadhy, N. Wenkam, D. Helber, Dosimetry, Tolerance and Shelf-Life Extension Related to Disinfestation of Tropical Fruits by Gamma Irradiation, Disinfestation of Fruit by Irradiation, pp. 43-57 IAEA (1971). See Reference B-9.

- C-10 Code of Federal Regulations, Title 21, Chapter
 I, Subpart F, Section 121.2543.
 See Reference II-2
- C-11 Committee on Food Protection, National Academy
 of Science, Radio Nuclides in Foods
 pp.95-97, Washington, D. C., (1973).

SECTION D: METHODS FOR DETERMINING ADDITIVE

Since there are no known detectable changes in composition of papaya treated at absorbed doses of less than the maximum absorbed dose of 75 krad there are no known analytical methods which can usefully provide objective, practical, reliable and quantitative indicators of "effects" dosimeters to measure absorbed dose within individual fruit. There are no successful reliable go/no go indicator methods to determine exposure of product to the dose range of less than 75 krad. Therefore, dose control during treatment will depend upon well established monitoring procedures as described in Section A.

Monitoring should consist of time cycle recordings of the package conveyor speed and dwell times which will in effect establish the irradiation exposure to the commodity once the irradiator and each specific package geometry to be used has been characterized and calibrated with "primary" chemical dosimetry. This will allow more rapid correction of out-of-process control than actual dosimetry. Correction will be made as the radio nuclide decays. Phantom packages with appropriately placed "secondary" dosimeters (previously cross-calibrated with the "primary" dosimeter) can also be run daily to directly verify total dose, dose rates, and dose distributions within the package.

SECTION E: SAFETY

(To be furnished)

Section F: Regulation

The USDA requests that a food additive regulation be issued permitting the use of gamma radiation as a means of disinfecting papaya fruit of certain fruit flies to the extent postulated by the proposed USDA regulation.

The proposed wording of this regulation is as follows:

121. Disinfestation treatment by low dose gamma radiation of fresh papayas.

Gamma radiation for the treatment of fresh papayas must be safely applied under the following conditions:

(a) The radiation source consists of sealed units containing the isotope cobalt-60 or cesium-137.

(b) The gamma radiation is used in a single treatment to provide an absorbed dose of between 26 krad to 75 krad to control infestation due to certain presently quarantined fruit flies.

(c) To assure safe use the label and labeling of the food shall bear, in addition to the other information required by the Act, the following statements:

(1) "Treated with ionizing energy" or "Treated with gamma energy", on retail packages.

(2) "Treated with ionizing energy - do not treat again" on wholesale packages or on invoices or bills of lading of bulk shipments. The word "radiation" may be substituted for "ionizing."

